Remarks

The Office Action dated May 5, 2008 has been carefully considered. Claims 2, 3, 8, 24 and 36 have been amended in a manner which is believed to remove the bases for the formal objections to these claims. With these amendments, it is believed that these claims are no longer objectionable and the Examiner is thanked for pointing out the problems in these claims.

Claims 1-5, 7-11, 13-17, 25, 26, 28, 30, 31 and 33-36 have been rejected as anticipated by Mai Patent No. 6,643,548. Mai is directed primarily to diagnosis of heart disease by collecting data which is stored and processed to assist in determining the disease state of a heart. Mai does make further reference to therapy, but only in a very limited way. At column 2, lines 56-64, a portion of Mai relied upon by the Examiner, Mai states as follows:

> "In accordance with a further aspect of the present invention, **when the device is a cardiac stimulation device** for delivering therapy, such as **pacing therapy** to the patient's heart, the device itself may adjust stimulation therapy responsive to the determined physiological parameter measurements. The stimulation therapy adjustment may take the form, for example, of pacing rate adjustments to assist the patient in breathing or in the removal of fluid from the lungs." (emphasis added)

The present invention is not directed to cardiac stimulation nor is it directed to pacing therapy. Rather, it is directed to the control of an aortic pulsatile heart assist device. The two types of therapies are fundamentally different. Cardiac stimulation therapy, such as pacing, involves sending electrical signals directly to the heart to correct various types of abnormal heart behavior such as fibrillation, etc. A heart requiring cardiac stimulation therapy will not necessarily need pumping assistance of the type described in the present application.

Conversely, a patient who needs heart assist therapy of the type described in the present application will not necessarily need cardiac stimulation therapy. In addition, unlike cardiac

stimulation therapy, the therapy of the invention of the present invention involves manipulation of the aorta, not the transmission of electrical signals to the heart itself.

There is absolutely no disclosure in Mai of a method involving pulsatile heart assist of the aorta nor is there any disclosure in Mai of any method of controlling a pulsatile heart assist device which is coupled to the aorta. Some of the rejected claims have been amended to make this distinction more apparent. For example, claims 1 and 4 have been recast as Jepson type claims such that the preamble of these claims must be taken into account as a meaningful element of the claims. The effect of Jepson type claims is explained in some detail in Rowe v. Dror, 112 F.3d 473, 479 (Fed. Cir. 1997) and in *Manual of Patent Examining Procedure*, Section 608.01m. As stated in the latter, the Jepson form of claim:

> "is to be considered a combination claim. The preamble of this form of claim is considered to positively and clearly include all the elements or steps recited therein as part of the claimed combination."

Thus, it is believed that the anticipation rejection based on Mai is not applicable to the claims as amended and withdrawal of this rejection is submitted to be appropriate.

Claims 6 and 32 have been rejected as unpatentable over Mai in view of the Jones publication from the *Journal of Biological Physics*. Jones is relied upon for its disclosure of sensing heart sounds in the range of 20-500 Hz. This disclosure in Jones does nothing to remedy the deficiencies in Mai pointed out above. Applicant does not purport to be the inventor of sensing heart sounds in the range recited in claims 6 and 32. Thus, it is respectfully submitted that these claims are patentable for the same reasons as those set forth above with regard to the rejection based on anticipation by Mai.

Claims 12 an 29 have been rejected as unpatentable over Mai in view of Larson Patent No, 5,722,930. Larson is relied upon for its disclosure of epicardial sensing leads. Applicant does not purport to be the inventor of such leads apart from the combination recited in claim 12. Larson's disclosure of this epicardial lead does nothing to remedy the deficiencies of Mai pointed out above.

With regard to claim 29, Larson is relied upon for its use of an implantable pump. The Examiner suggests that the combination of the pump of Larson with the device of Mai would be nothing more than an "update" of Mai. There is absolutely no basis for this suggestion in the prior art. The therapies of Mai and Larson are completely distinct from each other, a fact which is evident from Larson's disclosure at column 17, lines 51-60. It is there disclosed that pacemakers and heart assist pumps perform different functions to treat different disease states of the heart.

Furthermore, control of the pump of Larson is based solely on ECG readings and there is no disclosure or suggestion of using the combination of ECG readings and sound sensing as recited in claim 29 by reason of its dependency on claim 5. Thus, the Examiner's suggestion regarding updating Mai "by combining the electronics shown in Mai with the pump shown in Larson" has no basis. The suggested updating would be a massive transformation of Mai and it is submitted that this transformation would not be obvious to one skilled in the art. It is believed that the Examiner has gone farther than the law permits in looking for elements recited in claim 9 in different prior art references and then attempting to put them together in an impermissible attempted reconstruction of Applicant's invention. Claim 29 is believed to be patentable.

Claim 18 has been rejected as unpatentable over Mai in view of Luisada publication from the *Japanese Heart Journal*. Luisada teaches that a microphone can be positioned outside of the body of the patient which sounds can be correlated, to some extent, with heart functions. Applicant does not purport to be the first to invent the use of an external microphone to detect heart sounds. Much more importantly, Applicant does believe himself to be the inventor of the use of an external microphone in combination with the controller for an aortic pulsatile pump. Neither Mai nor Luisada nor their combination comprise such a method. Furthermore, and also of great importance, there is absolutely no reason to modify the system of Mai with an external microphone. The use of an external microphone in the system of Mai would make it undesirably cumbersome and would provide no advantage. Indeed, the combination of the 1977 technology of Luisada with that of the Mai patent, which was filed in 2000, would involve going backwards 23 years in time in the attempted modification of Mai.

In contrast, in Applicant's entirely different method of controlling an aortic pulsatile pump, it can be advantageous for some patients to use an external microphone to detect the S1 and S2 sounds made by the heart and use them, in combination with R-wave sensing to control the pulsatile pump. The combination of Mai and Luisada is far afield from this combination and it is submitted that claim 18 is plainly patentable over this combination of references.

Claims 19 and 20 have been rejected as unpatentable over Mai in view of Luisada and further in view of Pizon Patent No. 4,459,977 and Reeves Patent No. 5,337,752. The addition of Pizon and Reeves does nothing to remedy the deficiencies of the combination of Mai and Luisada.

First, it is important to note that Pizon and Reeves are directed to diametrically opposite systems. In the method of Pizon, the blood is pumped counter to the normal circulatory flow of blood, as can be seen from column 1, lines 14-16. In contrast, the method of Reeves pumps to assist a heart in its function of pumping blood in a direction of normal circulation. Stated differently, Pizon is a retro perfusion technology and Reeves is a concurrent flow technology. Thus, these references cannot rationally be combined. Furthermore, Reeves uses a pump powered by electricity whereas Pizon uses a mechanical pump.

It is also important to note that the Examiner's characterization of Pizon and Reeves is fundamentally inaccurate. Contrary to the Examiner's statement, Pizon does not disclose an external gas-driven extra-aortic balloon pump nor does it disclose the use of an external microphone placed in the lumen of a gas line leading to an extra-aortic balloon. There is no extra-aortic balloon disclosed in Pizon. Rather, the balloon pump of Pizon, which comprises balloon 8 and rigid enclosure 9 surrounds a flexible tube 3 which is connected to femoral artery 4 and coronary sinus 1. This flexible tube 3 is filled with blood, not gas. Furthermore, gas line 11 is part of a closed system which functions to exert pressure on balloon 8 as shown in Figures 5A, 5B and 3. There is absolutely no disclosure of a percutaneous gas line in Pizon.

Equally important, Reeves does not teach the use of an external microphone placed in the lumen of an extra-aortic balloon or gas line leading to an extra-aortic balloon. As a matter of fact, Reeves does not disclose an extra-aortic balloon of any sort. Rather, he discloses an intra-aortic electrically driven pump which, of course, has no balloon and no gas line and has no external microphone placed in such a lumen. The Examiner relies upon column 5, lines 31-42 of Reeves for this teaching, but there is absolutely nothing there or anyplace else in Reeves which

supports the Examiner's position. Neither Mai nor Luisada would have any interest in the use of the retro perfusion method of system of Pizon. The attempt to combine the retro perfusion of Pizon with the diagnosis and cardiac stimulation of Mai and Luisada appears to be entirely based on the disclosure in Applicant's specification. The statement by the Examiner that it would have been obvious to a person of ordinary skill to add an external gas-driven aortic balloon pump to Mai just because such pumps might have been well known as of 1984 is entirely baseless. Pizon does not disclose such pumps. Thus, even if Pizon were combined with Mai and Luisada, it would not result in the recited combination. The combination of Luisada with Mai makes no sense and would simply distort Mai's technology. Neither Mai nor Luisada has any pertinence to control of a pulsatile pump. The lengths to which the Examiner has gone in an effort to reconstruct the claimed invention go well beyond what is permitted by the law. The situation becomes even worse when Reeves is thrown into the mix.

Contrary to the Examiner's statement, Reeves does not teach placing an external microphone "in the lumen of the extra-aortic balloon or the gas line leading to the extra-aortic balloon." Reeves has no balloon or gas line. Rather, Reeves teaches nothing more than placing a microphone on the chest or appendage of a patient (column 2, line 27).

Furthermore, the purpose of the microphone of Reeves is to synchronize acoustic blood flow signals with ECG readings for diagnostic purposes. There is absolutely nothing in Reeves to suggest any use relating to control of a pump such as that of Pizon. Thus, the resulting combination is a mixture of unrelated references, both of which are not what the Examiner says they are. With regard to claim 20, the Examiner's statement that Reeves discloses the use of an implanted gas line and balloon as a stethoscope to detect heart sounds is just plain wrong. Once

again, Reeves discloses nothing more than putting a microphone on the chest or other appendage of a patient for diagnostic purposes. The Examiner's attempt to combine the unrelated diagnostic system of Reeves with the retro perfusion system of Pizon is a plainly improper attempt to combine two utterly unrelated references. Even worse, the notion that Reeves discloses a microphone in a sound conducting conduit of any sort is a fundamental misreading of Reeves.

In summary, the rejection of claims 19 and 20 over a combination of four unrelated and uncombinable references is in error and should be withdrawn.

Claims 21-23 have been rejected over the four references relied upon to reject claims 19 and 20 plus Meadows Patent No. 6,553,263.

Meadows is directed to an implantable pulse generator which can be used for spinal cord stimulation or other purposes. It is a self-contained unit which can be non-invasively programmed with hand-held programmer, these components being illustrated in Figure 2 as elements 100 and 202, respectively. Percutaneous extensions 132 can be connected, through an electrode array, to the implantable pulse generator so that a trial stimulator can be used to test the implantable pulse generator. Thus, Meadows has no relationship to control of an aortic pulsatile pump nor does it have any relationship to detection of wave or sound characteristics of a heart. The percutaneous extensions of Meadows are designed for connection to an electrode array but none of the remaining references disclose such a mode of connection. In spite of all this, the Examiner states that the percutaneous extensions of Meadows are "capable of being used as a percutaneous ECG lead to directly transmit the ECG signal to the controller, 140." This is a gross distortion of Meadows. The percutaneous extension of Meadows does not transmit

outward bound signals of any sort from the body, much less ECG signals. There is no mention of ECG signals in Meadows. Rather, the trial stimulator 140 of Meadows transmits inward bound signals to test the functionality of the implanted pulse generator 100 for a relatively short period of time. The trial stimulator is then disconnected and the implantable pulse generator then proceeds to operate on its own. It would be hard to imagine a system more remote from the present invention than that of Meadows and it is impossible to imagine how combination of Meadows with the remaining references could result in transmission of ECG signals. In fact, no such transmission of any signal outbound from the body is contemplated by Meadows and the trial stimulator 140 is not a controller.

With regard to claim 22, the Examiner's attempt to combine Meadows and Pizon is improper and makes no sense. The system of Pizon is a retro perfusion arrangement designed to push blood back into the heart. There is absolutely no need for a percutaneous extension to an ECG device in Pizon because Pizon does not have an internal ECG sensor. Thus, if Pizon did have a percutaneous lead, there would be nothing to which it could be connected. Furthermore, contrary to the Examiner's statement that "Pizon has a percutaneous gas line", he does not. Tubing 3 contains blood. The only gas line in Pizon is conduit 11 which is shown in Figures 1, 2 and 3. Gas line 11 is a part of a closed system which functions to exert pressure on an external balloon 8 as shown in Figures 5A and B. There is simply no percutaneous gas line in Pizon.

With regard to claim 23, the combination of Mai, Luisada, Pizon and Reeves with Meadows also makes no sense. As explained above, there is no purpose in using percutaneous leads in Pizon. In addition, Pizon and Reeves are directed to diametrically opposite procedures. Reeves uses a pump to assist the heart in its function of pumping blood in a direction of a normal

circulation system. Pizon is just the opposite. He pumps blood backwards, i.e., in the direction opposite to the normal blood flow, as plainly stated at column 1, lines 14-16. Mai and Luisada have absolutely nothing to do with pumping blood in any direction. Rather, they are diagnostic devices, with Mai also disclosing a cardiac stimulation function. Meadows not only has nothing to do with pumping blood, he also has nothing to do with heart diagnosis. Rather, Meadows is directed to an implantable pulse generator. The percutaneous leads of Meadows would serve no purpose in Mai, Pizon, Meadows or Luisada and are designed only for temporary use to assure proper programming of the implantable pulse generator. This collection of disparate references which have nothing to do with each other is respectfully submitted to be improper and is an erroneous basis for rejecting claims in this application.

Claim 24 has been rejected as unpatentable over Mai, Luisada, Pizon, Reeves and Meadows with the addition of Freed WO 98/51367. Freed discloses a releasable and sealable connection for a percutaneous gas line and for electrical communication. As explained above, Reeves and Pizon have no need for a percutaneous connection, much less a releasable and sealable connection. The same is true of Mai and Luisada. Meadows has no need for a percutaneous gas line and already has a releasable connection. Thus, the addition of Freed makes a bad situation worse by combining still another unrelated reference to the combination attempted by the Examiner. This rejection is erroneous and should be withdrawn.

Claim 27 has been rejected as unpatentable over Mai in view of Meadows. Meadows discloses a rechargeable battery but does not disclose a multi-channel digital signal processor and transmitter (DSPT). Rather, Meadows discloses a hand-held programmer 202 as one distinct item and a trial stimulator 140 as another item, each of which has totally different functions and

neither of which is connected to the other, although the HHP 202 can be linked to the trial stimulator, e.g., with an infrared link. Applicant does not purport to be the inventor of rechargeable batteries that can be recharged by induction, but the use of such a battery in Mai would be meaningless with regard to meeting the remainder of the terms of claim 27 which are directed to a method of controlling the operation of an aortic pulsatile heart assist device, not to diagnosis or cardiac stimulation as disclosed in Mai. Thus, the combination of Mai and Meadows falls far short of the invention of claim 27. Thus, it is respectfully requested that this rejection be withdrawn.

Newly-presented claims 37 and 38 are believed to be patentable over the prior art of record for the reasons set forth above. These are claims are directed, respectively, to a method of controlling an extra-aortic counter pulsational pulsatile heart assist device comprising a balloon and to an apparatus for controlling such a device. Each of the claims recites the steps of or the components needed to detect both an R-wave and a sound created by the heart and using them to control the pulsatile status of the extra-aortic heart assist device. Thus, it is believed that claims 37 and 38 are patentable.

It is believed that the present application is in condition for allowance and a favorable action is respectfully solicited.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 15-0665.

Respectfully submitted,

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